REMARKS

Claims 1-6 and 10-12 are pending; claim 1 has been amended.

As an initial matter, Applicants thank the Examiner for renumbering the claims.

Claim 1 has been amended to indicate that the produced dendritic cells are characterized by increased CD83 expression, increased CD86 expression, decreased CD115 expression, or decreased CD32 expression relative to the expression of these cell markers in the pluripotential cells. Support for these claim amendments can be found throughout the specification, for example, at page 27, lines 18-22.

None of the above-amendments adds any new matter to the Application as filed.

I. <u>Sequence Listing</u>

In response to the Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures (copy attached herewith as Appendix B), Applicants have amended the specification to insert the sequence listing which was filed in the parent application (Serial No. 08/600,483) on December 30, 2002 (Sequence Listing in paper form attached herewith as Appendix A). In accordance with the provisions of 37 C.F.R. §1.821(e), please use the last-filed computer readable form of the sequence listing filed in the parent application (Serial No. 08/600,483) as the computer-readable form for this Application.

II. Status of the Application

The Office Action has questioned whether this Application is a continuation or a continuation-in-part of the parent application (Serial No. 08/600,483) (see Office Action, p. 2, ¶4).

Applicants clarify for the record that this Application is a continuation of parent application (Serial No. 08/600,483).

Specifically, the Office Action has alleged that although the specification discloses a method for producing dendritic cells using a "maturation factor", the present claims recite the generic term "factor." (Office Action, p. 2, ¶4).

Applicants respectfully point out that in addition to "maturation factor", the term "factor" is also used in the Application as the substance which causes the production of mature dendritic

cells from immature dendritic cells (see, *e.g.*, specification at page 8, lines 4-8). Thus, Applicants should not be limited to using the term "maturation factor" in the claims since the term "factor" was supported in the Application as originally filed.

The Office Action has also asserted that the specification discloses a method for producing mature dendritic cells from immature dendritic cells (Office Action, p. 2, ¶4). Applicants note that the specification teaches that although immature dendritic cells can be produced by pluripotent cells, unless these immature dendritic cells are exposed to a factor (*e.g.*, a dendritic cell maturation factor), they will revert back to being pluripotential cells having characteristics similar to macrophages or monocytes (see, *e.g.*, specification at page 14, lines 16-24 and at page 22, lines 18-19). Indeed, Webster's New Collegiate Dictionary (G. & C. Merriam Co., 1981) defines "pluripotent" as "not fixed as to developmental potentialities: having developmental plasticity" (p. 878; p. 878 and coverpages attached herewith as Appendix C). Thus, it is Applicants' position that the immature dendritic cells, because they are not fixed as to developmental potentialities, are, in fact, pluripotential cells.

Additionally, and contrary to what is asserted in the Office Action, peripheral blood mononuclear cells (PBMCs) are <u>not</u> the only pluripotent cells disclosed in the Application. As discussed above, immature dendritic cells are also pluripotential cells. Moreover, the Application states that pluripotent cells are cells that have the potential of expressing either macrophage or dendritic cell characteristics (see, *e.g.*, specification at page 6, lines 10-12). Thus, while it's true that PBMCs are pluripotent cells, they are not the only type of pluripotent cell disclosed in the Application.

As this objection applies specifically to claim 2, Applicants respectfully direct attention to the specification at page 15, lines 5-10. There, the specification states, "The pluripotent cells....are present in blood as PBMCs...the pluripotential cells may also be obtained from any tissue in which they reside, including bone marrow and spleen tissues." Thus, the pluripotent cells need not be from the peripheral blood, but may rather be mononuclear cells from other locations, such as the spleen or the bone marrow.

As this objection applies to claim 4, Applicants direct attention to the specification at page 15, lines 10-12. There, the specification states, "These pluripotential cells typically express CD14, CD32, CD68, and CD115 monocyte markers." Moreover, at page 22, lines 18-19, the specification describes the re-adherence and reversion to monocytes by immature dendritic cells

upon removal from GM-CSF and IL-4. Thus, the specification provides monocytes as one non-limiting example of a pluripotent cell.

Finally, the Office Action opines that most of the cytokines listed in Claim 6 are not disclosed in the specification. Applicants respectfully point out that IL-4 is disclosed, *e.g.*, at page 15, line 14 and at page 22, line 17; IL-13 is disclosed, *e.g.*, at page 15, line 14; IL-1β is disclosed, *e.g.*, at page 52, lines 7-20; TNF-α is disclosed, *e.g.*, at page 37, lines 17-23 and at page 52, lines 7-20; IL-12 is disclosed, *e.g.*, at page 37, lines 17-23 and at page 52, lines 7-20; stem cell factor is disclosed, *e.g.*, at page 52, lines 7-20; and IL-15 is disclosed, *e.g.*, at page 37, lines 17-23.

Thus, Applicants respectfully aver that this Application is indeed a <u>continuation</u> of parent application (Serial No. 08/600,483), and that the current claims add no new matter to the Application as it was originally filed as parent application (Serial No. 08/600,483).

Rejections Under 35 U.S.C. §112, Second Paragraph

Claims 1-6 and 10-12 stand rejected under 35 U.S.C. §112, second paragraph, because the term "pluripotential cells" is allegedly vague and indefinite. Specifically, the Office Action has alleged that the term is not defined in the specification, and that only one example of pluripotent cells, namely PBMCs, is disclosed (Office Action, p. 3, ¶6).

Applicants respectfully traverse this ground for rejection.

Applicants respectfully point out that the term "pluripotent" is known to the ordinary college student to mean something that is "not fixed as to developmental potentialities: having developmental plasticity" (see Webster's New Collegiate Dictionary (G. & C. Merriam Co., 1981), p. 878; p. 878 and coverpages attached herewith as Appendix C). Thus, Applicants aver that one of ordinary skill in the art would understand that a pluripotential cell is one that has the potential of developing into a dendritic cell.

Moreover, as mentioned above, the Application teaches that pluripotent cells are cells that have the potential of expressing either macrophage or dendritic cell characteristics (see, *e.g.*, specification at page 6, lines 10-12). Thus, the term "pluripotential cells" is not interchangeable with the term "PBMCs". Rather, PBMCs are simply one type of pluripotential cells. Other pluripotential cells "may also be obtained from any tissue in which they reside, including bone marrow and spleen tissues" (specification, at page 15, lines 5-10).

Because the ordinarily skilled artisan, upon reading the specification and the claims, would not be confused by term, "pluripotential cells", this rejection should be reconsidered and withdrawn.

Claims 1-6 and 10-12 stand rejected under 35 U.S.C. §112, second paragraph, because the phrase "express characteristics of DCs" is allegedly vague and indefinite (Office Action, p. 3, ¶6).

Applicants have overcome this ground for rejection with the present amendment to claim 1, clarifying the characteristic(s) of dendritic cells produced by the method.

Based on these remarks, this rejection should be reconsidered and withdrawn.

Rejections Under 35 U.S.C. §102

Claims 1-6 and 10-12 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,994,126 ("the '126 patent").

Applicants have overcome this ground for rejection with the present amendment to claim 1.

The dendritic cells produced by the claimed method are characterized in that they have increased CD83 expression, increased CD86 expression, decreased CD115 expression, or decreased CD32 expression relative to the expression of these cell markers in pluripotential cells.

As the '126 patent fails to teach the production of a dendritic cell having any one of these characteristics, it cannot anticipate the present claims.

Accordingly, this ground for rejection should be reconsidered and withdrawn.

Claims 1-6 and 10-12 stand rejected under 35 U.S.C. §102(b) as being anticipated by Romani et al., *J. Exp. Med.* 180: 83-93, 1994 (hereinafter "Romani").

Applicants have overcome this ground for rejection with the present amendment to claim 1.

The dendritic cells produced by the claimed method are characterized in that they have increased CD83 expression, increased CD86 expression, decreased CD115 expression, or decreased CD32 expression relative to the expression of these cell markers in pluripotential cells.

As Romani fails to teach the production of a dendritic cell having any one of these characteristics, it cannot anticipate the present claims.

Accordingly, this ground for rejection should be reconsidered and withdrawn.

Rejections Under 35 U.S.C. §112, First Paragraph

Claims 1-6 and 10-12 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly not providing adequate written description to show that Applicants were in possession of a "factor" to use to produce dendritic cells from pluripotential cells (Office Action, p. 4-5, ¶11).

Applicants respectfully traverse this ground for rejection.

As an initial matter, Applicants point out that they are not claiming a factor. Rather, they are claiming a method using a factor. As discussed above, the specification has taught that a factor may be, for example, GM-CSF. It may also be another cytokine, or a combination of cytokines, and the specification has described how to identify additional factors (page 27, lines 1-30). Hence, it is the Applicants' position that the *precise* identity of the factor is irrelevant. Rather, what *is* relevant is that if the ordinarily skilled artisan cultures pluripotential cells in the presence of a factor in accordance with the method described in the specification, he will obtain mature dendritic cells, as characterized by their increased CD83 expression, increased CD86 expression, decreased CD115 expression, or decreased CD32 expression.

Applicants' specification has provided several working examples and extensive detail describing their pioneering claimed method for obtaining dendritic cells. Indeed, Applicants' specification has provided two sources for the factor, namely conditioned medium and fixed *Staphyloccus aureus* (SACS) (see, *e.g.*, page 47, line 14 through page 54, line 25). Further, Applicants have clearly described, in both the specification and the claims themselves, the dendritic cells which result from practicing the claimed method. Applicants respectfully aver that, following the teachings provided in the specification, the ordinarily skilled artisan would be able to arrive at the mature dendritic cells as described in the specification and the claims. Thus, it is Applicants' position that, based on the teaching of the specification, the ordinarily skilled artisan would conclude that Applicants did indeed possess the claimed invention at the time the Application was filed.

U.S. Serial No. 10/047,072 Amendment under 37 CFR §1.111

Thus, Applicants respectfully aver that the specification provides adequate written description support for claims 1-6 and 10-12. Accordingly, Applicants request reconsideration and withdrawal of this ground of rejection.

CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance. However, if the Examiner believes that any further discussion of this communication would be helpful, she is encouraged to contact the undersigned by telephone.

Respectfully submitted, HALE AND DORR LLP

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Attorney for Applicants

Date: October 2, 2003

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Appendix A

Sequence Listing in paper form

SEQUENCE LISTING

```
<110> Steinman, Ralph M.
      Bhardwaj, Nina
      Schuler, Gerold
<120> Methods and Compositions for Obtaining Mature Dentritic Cells
<130> MER-011(112917-138US1)
<140> US 08/600,483
<141> 1996-02-12
<160> 3
<170> FastSEQ for Windows Version 4.0
<210> 1
<211> 9
<212> PRT
<213> Influenza matrix peptide
<400> 1
Gly Ile Leu Gly Phe Val Phe Thr Leu
<210> 2
<211> 9
<212> PRT
<213> Human Immunodeficiency Virus Type 1
<400> 2
Ile Leu Lys Glu Pro Val His Gly Val
<210> 3
<211> 9
<212> PRT
<213> Human Immunodeficiency Virus Type 1
<400> 3
Ser Leu Tyr Asn Thr Val Ala Thr Leu
                 5
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Appendix B

Copy of the Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures

Ap | cation No.: 10/0/7,072

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

N	1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
	2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
	3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
	4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
	 The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
	6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
	7. Other:
Applicant Must Provide:	
X	An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
X	An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
X	A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).
For	questions regarding compliance to these requirements, please contact:
For	Rules Interpretation, call (703) 308-4216 CRF Submission Help, call (703) 308-4212 entIn Software Program Support Technical Assistance
	To Purchase Patentln Software703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY

Appendix C

Coverpages and page 878 from Webster's New Collegiate Dictionary (G. & C. Merriam Co., 1981)

Webster's New Collegiate Dictionary 150th Anniversary Edition



The G.&C. Merriam Company 1831-1981

Presented to



WEBSTER'S

New Collegiate Dictionary

a Merriam-Webster®

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reciprocating piece driven by or against fluid pressure; esp: PISTON d(2): a piece with a motion more or less like that of a ram or piston e: a rubber suction cup on a handle used to free plumbing traps and waste outlets of obstructions

traps and waste outlets of obstructions plunging fire n: direct fire from a superior elevation resulting in the projectiles striking the target at a high angle plunk \plonk\vb [imit.] vt 1: to pluck or hit so as to produce a quick, hollow, metallic, or harsh sound 2: to set down suddenly t PLUMP ~ vi 1: to make a plunking sound 2: to drop abruptly: DIVE 3: to come out in favor of someone or something

takes a singular verb) 2: relating to or consisting of or containing more than one or more than one kind or class (a ~ society)

takes a singular verb) 2: relating to or consisting of or containing more than one or more than one kind or class (a ~ society)—plural n—plural ly 1-3-l\(\frac{1}{2}\) adv
plural n—plural ly 1-3-l\(\frac{1}{2}\) adv
plural 2: the holding of two or more offices or positions (as benefices) at the same time 3 a: a theory, that there are more than one or more than two kinds of ultimate reality b: a theory that reality is composed of a plurality of entities 4 a: a state of society in which members of diverse ethnic, racial, religious, or social groups maintain an autonomous participation in and development of their traditional culture or special interest within the confines of a common civilization b: a concept, doctrine, or policy advocating this state — plu-ral-lat 1-last, adj or n — plu-ral-latic, plur-2-lis-tik, adj — plu-ral-latical-ly, tik, (2) lic, adv plu-ral-latic, plur-2-lis-tik, n, pl-ties 1 a: the state of being numerous c: a large number or quantity: MULTITUDE 2: PLURALISM 2; also: a benefice held by plurism 3 a: a number greater than another b: an excess of votes over those cast for an opposing candidate c: a number of votes cast for a candidate in a contest of more than two candidates that is greater than the number cast for any other candidate but not more than half the total votes cast plu-ra-lize \(\frac{1}{2}\) plu-ra-lize \(\frac{1}{2}\)

reproduction in some lower plants (as a fungus)
plus fours n pl: loose sports knickers made four inches longer
than ordinary knickers
'plush \plash n [MF peluche]: a fabric with an even pile longer
and less dense than velvet pile

2plush adj 1: relating to, resembling, or made of plush 2: notably luxurious — plush-ly adv — plush-ness n

plushy \plash-\alpha adj plush-ier; est 1: having the texture of or
covered with plush 2: LUXURIOUS, SHOWY — plush-i-ness n

plus-sage \blas-ii\ n: amount over and above another plus-sage \'plos-ij\ n: amount over and above another

covered with plush 2: LUXURIOUS. SHOWY — plush-kness n plus agg \bar | plus-ij\ n: amount over and above another plus sign n: a sign + denoting addition or a positive quantity Plu-to \bar | plut-(\partial \bar | n: amount over and above another plus sign n: a sign + denoting addition or a positive quantity Plu-to \bar | pluto \bar | n: pluto, fr. Gk Plouton 1: the Greek god of the underworld — compare Dis 2 [NL]: the planet farthest from the sun — see PLANET table
plu-to-ra-cy \pl\(\bar | \bar | \bar

nium 235, and that is fissionable with slow neutrons to yield atomic energy—see ELEMENT table

*plu-vi-al \plu-vi-al \quad j[L pluvialis, fr. pluvia rain, fr. fem. of pluvius rainy, fr. pluere to rain — more at FLOW]

1 a: of or relating to rain b: characterized by abundant rain 2 of a geologic change: resulting from the action of rain

*pluvial n: a prolonged period of wet climate (the ~s of the early Pleistocene)

plicare; akin to OHG flehtan to braid, L plectere, Gk plekein]: to twist together (~ two single yarns)

2ply n, pl plies 1 a: one of the strands in a yarn b: one of several layers (as of cloth) usu. sewn or laminated together c: one of the veneer sheets forming plywood d: a layer of a paper or paperboard 2: INCLINATION, BIAS.

3ply vb plied; ply-ing [ME plien, short for applien to apply] vt 1 a: to use or wield diligently (busily ~ing his pen) b: to practice or perform diligently (~ing his trade) 2: to keep furnishing or supplying something to (plied her with liquor) 3: to make a practice of rowing or sailing over or on (the boat plies the river) ~ vi 1: to apply oneself steadily 2: to go or travel regularly (a steamer ~ing between opposite shores of the lake).

Plymouth Rock \plim-3th\ n [fr. Plymouth Rock, on which the Pligrims are supposed to have landed in 1620]: any of an American breed of medium-sized single-combed dual-purpose domestic fowls

fowls

ply-wood \pli-wud\ n: a structural material consisting of sheets
of wood glued or cemented together with the grains of adjacent
layers arranged at right angles or at a wide angle

pm abbr 1 phase modulation 2 premium

Pm symbol promethium

PM abbr 1 paymaster 2 permanent magnet 3 police magistrate
4 postmaster 5 post meridiem 6 postmortem 7 prime minister
8 provost marshal

PMH abbr production per man-hour

pmk abbr postmark

pmk abbr postmark
PMLA abbr Publications of the Modern Language Association of

PN abbr payment
PN abbr promissory note
-pnea or -pnoea \((p)\)-ne-\(\)\(n\) comb form [NL, fr, Gk -pnoia, fr.
pnoia, fr. pnein to breathe]: breathing \(\(\begin{array}{c}\) hyperpnea\(\end{array}\)

pneum or pneumo comb form [NL, partly fr. Gk pneumo, (fr. pneuma), partly fr. Gk pneumo lung 1: air: gas (pneumothorax) 2: lung (pneumoctomy): pulmonary and (pneumogastric) 3: respiration (pneumograph) 4: pneumonia (pneumo-

pneu-ma \'n(y) "-m>\ n [Gk]: soul, spirit

\-i.k(a-)]\(\bar{e}\) adv

pneu-ma-tic-i-ty \n(y)\(\bar{u}\)-ma-'tis-at-\(\bar{e}\) n: a condition marked by the
presence of air cavities \(\sigma\) of bird bones\(\gamma\)

pneu-mat-ics \n(y)\(\bar{u}\)-mat-iks\\ n pl but sing in constr: a branch of
mechanics that deals with the mechanical properties of gases
pneu-ma-tol-o-gy \n(y)\(\bar{u}\)-ma-'til-\(\bar{e}\)-ig\\ n [NL pneumatologia, fr. Gk
pneumat-, pneumat-\(\bar{u}\) n \(\bar{u}\)-logia -logy]: the study of spiritual beings or phenomena

ings or phenomena
pneu-ma-tol-y-sis \-'täl-o-səs\ n [NL]: the process by which pneumatolytic minerals are formed
pneu-ma-tolytic \n(y)ii-mət-1-'it-ik, (,)n(y)ii-mat-1-\ adj [ISV]
: formed or forming by hot vapors or superheated liquids under
pressure— used esp. of minerals and ores
pneu-ma-tom-eter\n(y)ii-ma-'täm-ət-ər\ n 1: an instrument for
measuring the amount of force exerted by the lungs in respiration
2: SPIROMETER

pneumato-phore \n(y)\u00fc\u00e4mat-\u00e3-i\u00f6(\u00e3)r, \u00e4i\u00e9(\u00e3)r\u00e4n [ISV] 1: a muscular gas-containing sac that serves as a float on a siphonophore colony 2: a root often functioning as a respiratory organ in a marsh plant — pneu-mato-phor-ic \u00e4n(y)\u00fc-mat-\u00e3-f\u00f6r-ik, -\u00e4\u00e4r-\u00e4

pneu-mec-to-my \n(y)u-mek-to-me\ n, pl -mies [ISV]: the surgi-

から、かんなのながらいない

pneu-mec-to-my \n(y)\(\bar{u}\)-mek-to-m\(\bar{v}\), pl-mies [ISV]: the surgical removal of lung tissue pneu-mo-ba-cil·lus \n(y)\(\bar{u}\)-m\(\bar{v}\)-bo-'sil-os\(\bar{v}\), npl-cil·li \-\i also -\(\bar{v}\)-\(\bar{v}\)-mations (as pneumonia) of the respiratory tract pneu-mo-coc-cus \n(y)\(\bar{u}\)-ma-'k\(\bar{s}\)-\(\bar{v}\)-coc-ci \-'k\(\bar{s}\)-\(\bar{v}\)-\(\bar{s}\)-\(\bar{v}\)

adj
pneu-mo-co-ni-o-sis \'n(y)\"u-m\"o-1k\"o-n\"o-'\"o-ses\ n, pl-o-ses\ \-n\"s\"\"z\"\
[NL, fr. pneum- + Gk konis dust — more at INCINERATE]: a disease of the lungs caused by the habitual inhalation of irritant mineral or metallic particles — compare BLACK LUNG, SILICOSIS
pneu-mo-gas-tric \n(y)\"u-m\"o-gas-trik\ adj 1: of or relating to the lungs and the stomach 2: vAGAL
pneu-mo-graph \'n(y)\"u-m\"o-1graf\ n [ISV]: an instrument for recording the thoracic movements or volume change during respiration

pneu-mo-nec-to-my \n(y)\"u-m\"-nek-t\"-m\"\ n, pl -mies [Gk pneu-m\"\"\" n + ISV -ectomy]: excision of an entire lung or of one or more lobes of a lung

characterized by inflammation and consolidation followed by resolution and caused by infection or irritants

pneu-mon-ic \n(y)\u00fc-man-ik\ adj [NL pneumonicus, fr. Gk pneumonikos, fr. pneumono-ul-tra-mi-cro-scop-ic-sil-i-co-vol-ca-no-co-ni-o-sis \n(y)\u00fc\u00fc-ma-\u00fc-no-cl-tra-mi-kra-'skap-ik-'sil-i-()k\u00f6-()val-'k\u00e4-n\u00f6-\u00fc-s-\u00f3-s\u00e3s\u00e3 n [NL, fr. Gk pneumon + ISV ultramicroscopic + NL silicon + ISV volcano + Gk konis dust]: a pneumoconiosis caused by the inhalation of very fine silicate or quartz dust pneu-mo-tho-rax \n(y)\u00fc-ma-'th\u00f6(\u00fc)r-aks, -'th\u00f6(\u00fc)r-\u00e1 n [NL]: a state in which air or other gas is present in the pleural cavity and which occurs spontaneously as a result of disease or injury of lung